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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS	:	KIM, et al.
SERIAL NO.	:	10/016,812
FILED	:	December 7, 2001
FOR	:	RAPIDLY DISINTEGRABLE TABLET FOR ORAL ADMINISTRATION
EXAMINER	:	CHOI, Frank I. ART UNIT: 1616

To: Honorable Commissioner of Patents
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. SECTION 1.132

Sir:

I, Hyun-soo KIM, being a citizen of the Republic of Korea and presently residing at Backdoo Apt. 968-403, Sanbon-dong, Kunpo-si, Kyonggi-do, Korea, hereby declare as follows:

1. I am one of the inventors of the above-identified application.

2. I have performed a series of experiments to examine the inventive tablets comprising various pharmaceutically acceptable excipients, as follows.

3. Specifically, 10 g of domperidon and 1 g of colloidal silicon dioxide, each screened through a 30 mesh sieve, were mixed and added thereto were 117 g of spray-dried mannitol (Pearlitol SD 200, Roquette), 10 g of xylitol, 4 g of sodium starch glycolate, and 18 g of microcrystalline cellulose, each screened through a 20 mesh sieve. The mixture was further mixed with 7 g of crospovidone powder screened through a 20 mesh sieve, and then with 3 g of magnesium trisilicate, 3 g of magnesium stearate, each screened through a 40 mesh sieve (see Table 1). The resultant mixture was compressed into tablets using a single type tableting machine (Manesty F3, Manesty Machine Ltd.), to provide rapidly disintegrable tablets (Tablet A), each weighing 165 mg. The above procedure was repeated using the components shown in Table 1 to

obtain Tablets B to D.

The hardness and the disintegration time in oral cavity were measured for Tablets A to D, in accordance with the method disclosed in the specification of the present invention as originally filed (see page 13, line 11 to page 14, line 3).

<Table 1> (Unit : gram)

		Tablet A	Tablet B	Tablet C	Tablet D
Drugs	Domperidone	10	10		
	Simvastatine			20	20
Disintegrants	Spray-dried mannitol	117	200	150	186
	Crospovidone	7	12	10	10
Diluents	Xylitol	10		30	
	Sodium starch glycolate	4		6	7
	Microcrystalline cellulose	10			
Flavor			10		10
Lubricant	Magnesium trisilicate	3			5
	Magnesium stearate	3		8	5
	Colloidal silicon dioxide	1			
	Sodium stearyl fumarate		20		
Total weight (g)		165	232	224	243
Diameter (mm)		8	10	10	10
Number of tablets		1,000	1,000	1,000	1,000
Hardness (kp)		5	5	5	5
Disintegration time (second)		35	25	45	40

4. In addition, 20 g of famotidine and 2 g of colloidal silicon dioxide, each screened through a 30 mesh sieve, were mixed and added thereto were 130 g of spray-dried mannitol (Pearlitol SD 200, Roquette) and 20 g of dextrin, each

screened through a 20 mesh sieve. This mixture was further mixed with 12g of crospovidone powder, screened through a 20 mesh sieve, and then with 3g of magnesium trisilicate, 3g of magnesium stearate and 10g of orange flavour, each screened through a 40 mesh sieve (see Table 2). The resultant mixture was compressed into tablets using a single type tableting machine (Manesty F3, Manesty Machine Ltd.), to provide rapidly disintegrable tablets (Tablet E), each weighing 200 mg.

The above procedure was repeated using the components and active ingredients shown in Table 2 to obtain Tablets F to H according to the present invention.

<Table 2> (Unit : gram)

		Tablet E	Tablet F	Tablet G	Tablet H
Drugs	Famotidine	20	20	20	20
Disintegrants	Spray-dried mannitol	130	130	130	130
	Crospovidone	12	12	12	12
Diluents	Desrin	20			
	Dextrose		20		
	Cellulose			20	
	Lactose				20
Flavor (orange flavour)		10	10	10	10
Lubricant	Magnesium trisilicate	3	3		3
	Magnesium stearate	3		8	3
	Colloidal silicon dioxide	2	2		2
	Sodium stearyl fumarate		3		
Total weight (g)		200	200	200	200
Diameter (mm)		10	10	10	10
Number of tablets		1,000	1,000	1,000	1,000
Hardness (kp)		5	5	5	5
Disintegration time (second)		43	40	48	45

5. Tables 1 and 2 show that in accordance with the present invention, various excipients as well as those disclosed in the present specification as originally filed also can provide tablets which disintegrate within 60 seconds.

6. I hereby declare that all statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of United States Code and that such willful false statements may jeopardize the validity of the application or any patents issuing thereon.

Further deponents saith not.

Date: 4th day of December, 2005

Hyun Soo Kim

(Hyun-soo KIM)